5. 510(k) SUMMARY

DATE: September 7, 2011

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

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DEVICE NAME: CytoGuard™ Closed Luer Connector

COMMON OR USUAL NAME: Closed Luer Connector, Needle free

DEVICE CLASSIFICATION: Class II, per 21 CFR §880.5440, Product Code: FPA

PREDICATE DEVICES: Spiros™, ICU Medical Inc., K070532, Class II, FPA, 880.5440, Spinning Spiros™, ICU Medical Inc., K082806, Class II, FPA, 880.5440, CML ™, ICU Medical Inc., K051437, Class II FPA, 880.5440

DESCRIPTION: CytoGuard is a needle-free, bi-directional flow, luer connector that is swabable, MRI Safe and does not contain PVC, DEHP, or natural rubber latex. The CytoGuard™ Closed Luer Connector is designed to be used by healthcare professionals during medication preparation, admixture, fluid transfer, administration or disposal. Using CytoGuard's female luer end CytoGuard is attached to a dosing device's male luer connector, creating a luer locking connection. With the CytoGuard attached, the dosing device is provided with a closed fluid path due to the presence of the CytoGuard's internal valve. The closed valve helps to reduce inadvertent fluid exposure to patients, clinicians and healthcare personnel.

When the CytoGuard's male luer nut is connected to a standard female luer, the fluid path is opened and allows for the movement of fluid. When the female luer is disconnected from the proposed device, the valve and fluid path closes, preventing the flow of fluid through the CytoGuard.

The female luer end of the CytoGuard possesses a spinning locking feature which will not allow the device to be easily removed, further aiding the reduction of fluid exposure. This feature helps to reduce the risk that the female luer end may inadvertently become disconnected or be removed from the male luer of the dosing device.

To further assist in the appropriate use of the device, the male luer nut has been colored a translucent orange to alert users which end of the device that connections and disconnections can be made. The Instructions for Use references an "orange end" to aid in the easy identification of this part of the device.

The CytoGuard will be available for sale as an individually packaged item and a non luer-activating dust cover cap to prevent touch contamination is provided as a separately sold accessory for the CytoGuard for use during transport.

INTENDED USE:

The CytoGuard™ Closed Luer Connector is a bi-directional flow, needle-free, swabable luer access device used as an accessory to an administration device. It is intended for the administration of parenteral fluids, medication (including hazardous drugs), blood and blood products. With the CytoGuard attached to the standard male luer of a dosing device or container, the CytoGuard valve is in a closed position. Upon connection of its male luer fitting to the female luer fitting of a patient's administration set or catheter, the valve opens to allow medication delivery to the patient. The fluid path then closes, upon disconnect.

SUBSTANTIAL EQUIVALENCE:

Three predicate devices are utilized for substantial equivalence, ICU Medical Inc.'s Spiros™ (K070532), Spinning Spiros™ (K082806) and CML™ (K051437).

The Cytoguard Closed Luer Connector has similar intended uses to ICU Medical's Spiros, Spinning Spiros, and CML in that they each act as a closed male luer that provides access for the administration of fluids from a container (or dosing device) to the patient. Each of these devices has a normally closed design that is intended to prevent the leakage of fluid or ingress of air when in an inactivated state. When activated, they all provide a 2-way fluid flow. The CytoGuard and Spiros devices contain polycarbonate female luers.

Similar to the Spinning Spiros, the CytoGuard has a locking feature on the female luer end to prevent the device's disconnection during use.

Each of these devices has an open and closed state; however, the mechanism used to achieve it differs between the proposed and predicate devices. Therefore, performance testing has been conducted. In addition, testing was performed to support an expanded variety of usage conditions of the CytoGuard. Several different fluids were evaluated for compatibility, including blood, general IV fluids, and chemicals identified on the "NIOSH Alert" drugs list, publication number 2004-165 dated September 2004 which is provided within this submission.

CONCLUSION:

Testing was conducted to demonstrate the performance of the CytoGuard Closed Luer Connector and substantial equivalence with the predicate devices: ICU Medical's Spinning Spiros™, Spiros™ and CML™. Functional performance testing, a simulated clinical use study, and testing of the locking feature and colored design features of the proposed device, have each demonstrated that the CytoGuard Closed Luer Connector does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 6 2011

Ms. Angela J. Caravella
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
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Allentown, Pennsylvania 18109-9341

Re: K112636
Trade/Device Name: CytoGuard™ Closed Luer Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 7, 2011
Received: September 9, 2011

Dear Ms. Caravella

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112636

Device Name: CytoGuard™ Closed Luer Connector

Indications For Use:

The CytoGuard™ Closed Luer Connector is a bi-directional flow, needle-free, swabable luer access device used as an accessory to an IV Administration Set. It is intended for the administration of parenteral fluids, medication (including hazardous drugs), blood and blood products. With the CytoGuard attached to the standard male luer of a dosing device or container, the CytoGuard valve is in a closed position. Upon connection of its male luer fitting to the female luer fitting of a patient's administration set or catheter, the valve opens to allow medication delivery to the patient. The fluid path then closes, upon disconnect.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 11/30/4

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 112636